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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/037,616 | 01/02/2002 | Priscilla Anne Furth | 08830-002003 | 7943 |

7590 06/02/2003

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[REDACTED] EXAMINER

KETTER, JAMES S

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1636

10

DATE MAILED: 06/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-----------------|--------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/037,616 | FURTH ET AL. |
| | Examiner | Art Unit |
| | James S. Ketter | 1636 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 03 March 2003.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-12 and 19-21 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-12 and 19-21 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

| | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. | 6) <input type="checkbox"/> Other: _____. |

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12 and 19-21 stand, and newly filed 22 and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of gene transfer for non-therapeutic purposes and for genetic immunization, i.e., vaccination with a composition comprising a nucleic acid segment which expresses the antigen of interest, does not reasonably provide enablement for methods of gene therapy other than genetic immunization, i.e., embodiments encompassed by steps from groups "(a)", "(b)" and "(i)" (as now identified, after the amendment filed 13 March 2002), for reasons of record set forth in Paper No. 7, mailed 6 November 2002.

At the paragraph bridging pages 4 and 5 of the amendment filed 13 March 2003, Applicants argue that embodiments "(a)" and "(b)" do not involve gene therapy, but merely the destruction of cells. However, while the purpose of (a) may be merely to destroy cells, the destruction of such cells might encompass the expression of stably integrated DNA constructs, as the phrase is very broad. Such methods would be subject to the technical difficulties set forth for gene therapy methods in the previous Office Action. With respect to (b), again, the phrase is very broad, and would encompass any methods requiring stable or long-term gene expression, and thus would also be subject to said technical difficulties. With respect to (i), Applicants argue, at the first full paragraph at page 5, that inducing wound healing does not mean healing. First, it is not apparent that this is a valid distinction, as inducing an event is synonymous with

causing the event. Second, if a therapeutic use is not asserted, then the purpose of the claim is not apparent, and as such, one of skill would not be able to use the invention. Applicants argue, further along, that the use of the invention will trigger an immune response, which will induce healing. However, no support for such an assertion, either in the specification, or in the art, is of record. Furthermore, the phrase is such that gene therapy methods of inducing (or causing) wound healing are clearly encompassed, and as such, an attempt to practice such an embodiment would have encountered the technical problems set forth in the previous Office Action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 stands rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record set forth in paper No. 7. The term “specific manner” remains unclear.

At page 6, third paragraph, Applicants argue that in Miles Labs, the Federal Circuit held that if one of skill in the art would understand the bounds in light of the specification , then the claim is definite. Applicants then submit that “specific manner” means that each combination of elements would lead to a specific manner of expression relative to every other potential variation. However, it is not clear that this would be so. First, there is no evidence that one of skill would have interpreted the claim only in this manner. Indeed, one of skill might have read the claim as set forth in the previous Office Action, i.e., that some intended but unclaimed

manner were intended. Second, if the same expression pattern were seen for different embodiments, then this argument would be incorrect, and the term would still be indefinite. Since the existence of the same expression pattern between at least two different embodiments is at least a formal possibility, the term remains unclear for this reason as well, and the claim, therefore, is indefinite.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted directly to the Examiner by facsimile transmission at (703) 746-5155. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94

Art Unit: 1636

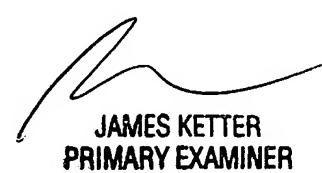
(December 28, 1993)(see 37 CFR ' 1.6(d)). To send the facsimile to the Art Unit instead, the Art Unit 1636 Fax number is (703) 305-7939. NOTE: If Applicant does submit a paper by fax to this number, the Examiner must be notified promptly, to ensure matching of the faxed paper to the application file, and the original signed copy should be retained by Applicant or Applicant's representative. (703) 308-4242 or (703) 305-3014 may be used without notification of the Examiner, with such faxed papers being handled in the manner of mailed responses. Applicant is encouraged to use the latter two fax numbers unless immediate action by the Examiner is required, e.g., during discussions of claim language for allowable subject matter. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (703) 308-1169. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Jsk
May 28, 2003



JAMES KETTER
PRIMARY EXAMINER